

Application No. 10/805,816  
Amendment dated April 18, 2007  
Reply to Office Action dated October 18, 2006

### **REMARKS/ARGUMENTS**

The Office Action dated October 18, 2006, has been reviewed in detail and it is noted that Claims 1 and 3-24 are pending in the application. Claim 1 has been amended to correct a typographical error. Claims 11, 12, 13 and 24 have also been amended herein.

#### **Amendments to the Specification:**

The specification has been amended herein to include in paragraph [0001] the names of the parties to a referenced joint research agreement. Paragraph [0017] has been amended to correct a typographical error.

#### **Examiner Interview:**

The undersigned would like to sincerely thank the Examiner for the courtesies extended during a telephonic interview between the Examiner and the undersigned on February 1, 2007. During that interview the instant outstanding Office Action of 10/18/06 was discussed, and the undersigned suggested to the Examiner that the finality of this office action should be withdrawn. The undersigned pointed out to the Examiner that new art had been applied against some of the claims, and that these claims had only been previously amended as to form. The Examiner agreed with the undersigned that because of the new rejection basis against these claims, the finality of the 10/18/06 Office Action should be withdrawn.

Based on the above, the instant Amendment and Remarks are written as if responding to a non-final Office Action. The telephonic interview is further summarized below in the section entitled "Recordation of the Substance of the Telephonic Interview."

#### **Claim Rejections – 35 USC § 101:**

In the outstanding Office Action Claims 11-12 were rejected under 35 U.S.C. 101. Specifically, the Examiner stated:

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*Claims 11-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 11-12 do not represent a product resulting from a process such as a machine or article of manufacture resulting from a manufacturing process or a composition from a synthesis process. Rather they represent a decision, per definition provided in para [0023] in the specification. A decision in and of itself is representative of an intangible, that is a mental state or conviction or belief, and so cannot be patented. A decision process such as embraced by the further step of deciding or diagnosing or treating or withholding treatment on the other hand is a legitimate part of an overall method process and can be claimed as such. Suggest change claims 10-11 to wordings representative of such steps.*

In response thereto, claims 11-12 have been amended in a manner believed to overcome this rejection. (Please note that the applicant worked under the assumption that when the Examiner referenced claims 10-11 in the final sentence above, he had actually intended to reference 11-12).

Based on the above, reconsideration and withdrawal of the present rejection are respectfully requested.

**Double Patenting/Terminal Disclaimer:**

The Examiner again provisionally rejected Claims 1, 3-24 on the grounds of double patenting. Specifically, the Examiner stated:

*Claims 1, 3 - 24 are again provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 10/911,755 in view of Michaeli (US6328694) for reasons set forth in the earlier office action. This is a provisional obviousness-type double patenting rejection.*

*With respect to applicants' argument that the '755 application has not been examined or patented, this is a provisional rejection predicated on the position that conflicting claims present in two applications prevents allowance of either set of claims. With respect to dates, such a rejection is made irrespective of dates since the applications should they issue may be separately assigned.*

In response, without addressing the merits of the Examiner's rejection, the Applicants are submitting herewith a Terminal Disclaimer in compliance with 37 C.F.R. § 1.321, as well as a Statement Pursuant to 35 U.S.C. § 103 (c), as amended by the CREATE Act, attesting that the

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instant application and co-pending application were both made as a result of activities undertaken within the scope of a joint research agreement. Additionally, the specification has been amended herein to reference the parties to this agreement.

Based on the above, it is respectfully submitted that this provisional double patenting rejection is now moot; accordingly, reconsideration and withdrawal are respectfully requested.

**Claim Rejection Under 35 U.S.C. §112:**

The Examiner has rejected Claims 1 and 3-12 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Specifically, the Examiner stated, inter alia:

*Claims 1 and 3-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, there is no teaching of manipulating the sequence of signal reception so that amplitude changes of the sequence at a constant frequency correspond to phase changes of the sequence.*

*This is a new matter rejection, see MPEP Section 2163.06 Section I.*

In response thereto, the Applicant respectfully submits that support for the referenced language in the claims, specifically the features of “converting the ultrasonic sequence into an electrical sequence;” and “mathematically manipulating the electrical sequence such that amplitude changes of the manipulated sequence, at a substantially constant frequency, correspond to phase changes of the ultrasonic sequence” as currently recited in Claim 1, was indeed described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. The Examiner is respectfully referred to the embodiment of the instant invention described in paragraphs [0017]-[0019]. Specifically, Paragraphs 17- 19, state:

“[0017]The data obtained from the captured reflected ultrasonic waves 32 are mathematically manipulated to differentiate the separate layers of the body, both inside and outside of the body compartment 20. Mathematical manipulations include organization and processing of the data in any appropriate manner that defines these layers. Preferably, the mathematical manipulation of the captured ultrasonic waves includes Fourier Transform manipulation. The Fourier Transform manipulations of the data allow categorization of pressure build-up in the interrogated body compartment. As Compartment Syndrome is most prevalent in arms and/or legs, these body masses are typically investigated, although other body

compartments 20 also may be interrogated for pressure buildup. Aspects of tissue characterization are described in United States Patent No. 5,746,209 to Yost et al., entitled "A Method of and Apparatus for Histological Human Tissue Characterization Using Ultrasound," the disclosure of which is hereby incorporated by reference as if set forth in its entirety herein.

"[0018] With the transducer 40 positioned on, and transmitting ultrasonic waves 30 into, the skin 22, body compartments 20 are interrogated with the capture of the reflected ultrasonic waves 32. The apparatus 10 of the present invention can include either identifying a decrease in the captured imparted ultrasonic waves or identifying a ratio of low-frequency amplitudes to high frequency amplitudes present in the mathematical manipulation of the captured ultrasonic waves for categorization of the CP build-up.

"[0019] In operation, as shown, the transducer 40 is energized with an electrical pulse which generates the ultrasonic pulse (UP) incorporating the ultrasonic wave 30. The UP 30 travels through the skin 22 and into the underlying tissues in the region of the compartment 20 as well as through the compartment 20, into the tissues contained by the compartment 20. Reflections 32 occur at each impedance discontinuity 32a, 32b, 32c, 32d, or each tissue interface, and are received at the transducer 40 in the sequence which they occur. The transducer 40 converts the ultrasonic sequence received back from the segment into an electrical sequence which can be amplified and sent to the oscilloscope to be digitized and displayed. For simplicity and speed of processing, the scope can perform and display the Fast Fourier Transform (FFT) on the sequence. Of note, the sequence and reflected sequence are partially regular over this segment, with this regularity showing on the FFT as a relatively larger amplitude of received signal at some specific frequency  $f_1$ . With the pressure in the compartment 20 within normal limits, the regularity of the sequence will be perturbed during heart beats, with this perturbation causing a change in the amplitude at  $f_1$ , indicating blood flow in the muscle tissue at those blood vessels which give rise to the constructive interference shown as a peak in the Fourier transform. If the pressure in the compartment 20 is sufficiently high, then flow through the BVN is impeded. During this condition the long term regularity is increased, and more peaks become prominent especially at the lower frequencies. Occasionally, and momentarily, the order disappears from the FFT, only for the order to return. This permits the Windkessel condition to be identified and timed. If these disturbances are non-existent, or occur too infrequently, then tissue viability is at risk, and surgical intervention may be needed. (*emphasis added*)"

It is respectfully submitted that based on the above specification language, it would be clear to someone with skill in the art that the instant specification teaches "mathematically manipulating the electrical sequence such that amplitude changes of the manipulated sequence, at a substantially constant frequency, correspond to phase changes of the ultrasonic sequence," so as to enable them to make and use the instant invention. That is to say, it is submitted that in light of the language of the specification, one skilled in the art would know that in the described

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embodiment, amplitude changes of the mathematically manipulated sequence (such as through FFT) at a substantially constant frequency, would correspond to phase changes of the ultrasonic sequence, as recited in Claim 1. Therefore, it is respectfully submitted that 1 and 3-12 do comply with the enablement requirement.

Based on the above, reconsideration and withdrawal of the present rejection are respectfully requested.

**Claim Rejections - 35 USC § 102:**

The Examiner has rejected Claims 13-14, 16, 18, 20-22, and 24, under 35 U.S.C. 102(b). Specifically, the Examiner stated:

*Claims 13-14, 16, 18, 20-22, 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Massie (US3885551). Massie is directed to an ultrasound Doppler system for assessing pressure buildup of the brachial artery (which is anatomically housed within the anterior (flexor) compartment of the arm i.e., an osteo-fascial compartment) with mathematical manipulation of the received ultrasound signal with respect to bandpass and thresholding and table conversion to a manometer numeric. Massie in effect uses a transducer receiver for a pulsatility analysis and displays the results.*

*{alternately stated, the Examiner is maintaining that the claims as amended pertain to an ultrasound blood pressure cuff analyzing the principal blood pressure effect in a limb compartment.}*

In response, the Applicant respectfully contends that the neither an ultrasound blood pressure cuff nor the Massie reference anticipate the instant invention as recited in amended independent claims 13 and 24. The Massie reference, like a standard blood pressure cuff, discloses the use of a cuff to apply external pressure to occlude arterial blood flow. The Massie reference discloses the monitoring of “the behavior of the arterial wall under cuff pressure with a doppler ultrasonic exploratory unit which basically is a motion detection system...” (Massie column 3, lines 1-4, *emphasis added*). Massie states:

“An advantage of the Doppler ultrasound technique is that information from stationary objects is ignored whereas signals are obtained from moving structures only. The Doppler shift signal is at an audio frequency which is proportional to the instantaneous

velocity of the reflecting target's motion with respect to the transmitting ultrasonic transducer....A typical pneumatic system employed for occluding the brachial artery might include a conventional automated electro-pneumatic system (not shown) to rapidly inflate and then gradually deflate the cuff such as by a relief valve 24....underneath the cuff and in contact with the arm is an ultrasonic transducer assembly 30 used in detecting arterial wall movements about artery segment 29 to be occluded" (Massie, column 3 lines 31-62, emphasis added .

Claim 13, as amended herein, recites:

An apparatus for non-invasively measuring pressure build-up in one or more body compartments that encase muscular tissue, comprising:

- (a) a transmitting device for imparting ultrasonic waves into one or more body compartments that are not being subjected to externally applied blood flow occluding pressure;
- (b) means for positioning the transmitting device adjacent to the one or more body compartments effective for imparting the ultrasonic waves therein;
- (c) means for capturing reflections of the imparted ultrasonic waves and converting the reflected waves into electrical signals;
- (d) means for mathematically manipulating the electrical signals; and,
- (e) means for categorizing pressure build-up in the one or more body compartments from the mathematical manipulations.

It is respectfully submitted that the Massie reference does not anticipate the features of "non-invasive" apparatus comprising "a transmitting device for imparting ultrasonic waves into one or more body compartments that are not being subjected to externally applied blood flow occluding pressure." To the contrary, as set forth above, the application of externally applied occluding pressure is a necessary component of the Massie invention to enable the audio monitoring of the behavior, or instantaneous motion, of the arterial wall under varying cuff pressure. Because both conventional blood pressure cuffs and the Massie reference require the invasive occlusion of blood flow in order to monitor blood pressure, it is respectfully submitted that they do not anticipate amended independent Claim 13. Because dependent Claims 14, 16, 18, and 20-22 depend from what is believed to be an allowable base claim, Claim 13, it is

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believed that Claims 14, 16, 18, and 20-22 and 24 are also allowable by virtue of this dependence.

Likewise, because independent Claim 24 has been amended to include the same limitations now contained in Claim 13; therefore, for the same or similar reasons as set forth immediately above in reference to Claim 13, amended Claim 24 is also believed to fully distinguish from both the Massie reference and a conventional ultrasonic blood pressure cuff, and thus Claim 24 is also believed to be in condition for allowance.

In light of the above, reconsideration and withdrawal of the instant rejection are respectfully requested.

**Claim Rejections - 35 USC § 103:**

The Examiner has rejected Claims 15, 17, 19, and 23 under 35 U.S.C. 103 (a). Specifically the Examiner stated:

*Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Massie in view of Hohlweck (US 4635198) insofar as, pursuing the blood pressure cuff system applicability, it would have been further obvious in view of the latter to provide a gel couplant chamber 25 to the forward face of Massie's transducers in order to assure transfer of the ultrasound energy into tissue.*

*Claims 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Massie as applied to claim 13 above, and further in view of Welkowitz et al (US 5101828) insofar as the latter would teach using ultrasound arm-cuff based measurements in association with FFT-derived ratios to analyze hemodynamic parameters related to blood pressure.*

*Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Massie as applied to claim 22 above, and further in view of Weissman et al (US 6308715) insofar as the latter would teach that use of time reversal techniques diminishes noise and increases sensitivity regarding ultrasound signal processing, see col. 16.*

In response, it is submitted that because each of these claims depends from what is believed to be an allowable base claim, Claim 13 (which base claim is believed to fully distinguish over the Massie reference for the reasons set forth above); therefore, Claims 15, 17, 19 and 23 are believed to be in condition for allowance as well by virtue of this dependence.

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Based on the above, reconsideration and withdrawal of the present rejection are respectfully requested.

**Recordation of the Substance of the Telephonic Interview:**

In order to render the Amendment complete, the following is a recordation of the substance of the telephonic interview conducted with the Examiner on February 1, 2007:

- 1) No exhibits were shown
- 2) Primarily independent Claim 13 was discussed
- 3) The fact that new prior art (Massie, US 3885551) was applied against Claim 13 was discussed, the actual substance and relevance of this art was not discussed.
- 4) The withdrawal of the finality of the instant 10/18/06 Office Action was discussed
- 5) It was suggested by the undersigned that because a new rejection basis (new art) had been applied against some of the claims, for example, Claim 13, which had only been amended based on form, that the finality of the Office Action should be withdrawn.
- 6) none
- 7) The outcome of the interview was the Examiner agreed that the finality of the instant Office Action should be withdrawn (as set forth in the Examiner's Interview Summary).

**Leave to Delay Treatment of Formal Objections Until Allowable Subject Matter is Indicated:**

In accordance with 37 C.F.R. 1.111, it is hereby requested that any objections or requirements not fully treated and set forth in the outstanding Office Action that relate to form and are not necessary to further consideration of the now pending claims be held in abeyance until allowable subject matter is indicated.

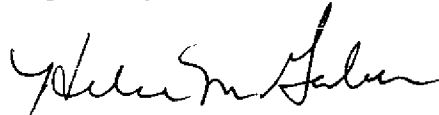


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**CONCLUSION**

It is submitted that the Applicants have submitted new and unique Ultrasonic Apparatus And Method to Assess Compartment Syndrome. In view of the above, it is submitted that Claims 1 and 3-24 are in condition for allowance. Therefore, it is requested that a Notice of Allowance be issued at an early date.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Helen M. Galus", written in a cursive style.

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